

K 961362

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510 (K) Submission
Telelink telephonic ECG receiving interface

510(K) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements: Regulation par. 807.92, effective March 14, 1995.

1. Submitter

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2. Device

Proprietary name: Telelink
Common name: ECG telephonic receiving interface.
Classification name: Transmitters and receivers electrocardiograph, telephone.

The Telelink is a battery powered ECG telephone receiving interface that is capable of transferring the transtelephonic ECG, received over the telephone, to a conventional single trace ECG recorder.

3. Predicate device

Aerotel H3000 transtelephonic ECG receiving console, 510(K): #K930314

Telelink

4. Description:

The Telelink is a battery powered interface which is intended to be used by a physician or an ECG technician to convert an ECG signal received via the telephone to an analog ECG signal recordable on the physician's conventional single trace ECG recorder.

The ECG signal can be sent over the phone by any of Aerotel's transtelephonic recorders / transmitters such as:

HeartView (510(K) # K950004)

H1001 (510(K) # K931020)

H2002 (510(K) # K915624)

or equivalent. These units have been cleared for sale in the United States by the FDA.

The Telelink has two connections; one of these is connected to the telephone's handset via an acoustic coupler (included) which is placed on the speaker of the handset; the other connection is attached to the single-trace ECG recorder in the physician's office via the recorder's patient cable by using only 3 wires of the patient cable.

After activating the recorder, all received ECG leads from the telephone, will be routed to the recorder which will print them out, one after the other, in the sequence in which they have been transmitted.

5. Intended use

The Telelink is a battery powered device intended to be used by the physician in his office, for the transfer of an ECG signal received over the telephone from a compatible transmitter, to a conventional single trace ECG recorder in the physician's office. The patient has no contact with the Telelink, and it does not affect him in any way.

6. Comparison

The Telelink has the same intended use as Aerotel's Heartline Receiving Console (510(K) # K930314). Its realization differs in that the Telelink does not have memory, is not PC - based, records on a conventional electrocardiograph, and is not software operated.

Telelink

Performance Data

(a) Non clinical tests

Non clinical tests provided include bench tests of frequency response, temperature stress, electromagnetic immunity and shock tests. There is no leakage current issue because the device is battery operated, and not connected to a patient.

(b) Clinical tests

Electrocardiograms were taken from three volunteers transmitting over the phone 3 and 12 lead ECG (by Aerotel HeartView recorder / transmitter 510(K) # K950004) and printing them out on an ECG recorder model MICRORULER, CARDIETTE, Elettronica Trentina.

The electrocardiograms were compared to those received on Aerotel's Heartline receiving console (510(K) # K930314) - the predicate device. The electrocardiograms from the two systems are equivalent in quality and diagnostic utility.

(c) Conclusion

The conclusion drawn from these tests is that the Telelink is equivalent in safety and efficacy to its predicate device.

Photograph

